

## PATENT COOPERATION TREATY

PCT

## NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Commissioner  
US Department of Commerce  
United States Patent and Trademark  
Office, PCT  
2011 South Clark Place Room  
CP2/5C24  
Arlington, VA 22202  
ETATS-UNIS D'AMERIQUE  
in its capacity as elected Office

Date of mailing (day/month/year) 03 January 2001 (03.01.01)	
International application No. PCT/US00/08354	Applicant's or agent's file reference SEA-6-7-PCT
International filing date (day/month/year) 30 March 2000 (30.03.00)	Priority date (day/month/year) 31 March 1999 (31.03.99)
Applicant SHOFNER, F., Michael, II et al	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:  
31 October 2000 (31.10.00)

☐ in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was  
☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer S. Mafla Telephone No.: (41-22) 338.83.38
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# PATENT COOPERATION TREATY

**PCT**

## NOTIFICATION OF THE RECORDING OF A CHANGE

(PCT Rule 92bis.1 and  
Administrative Instructions, Section 422)

From the INTERNATIONAL BUREAU

To:

SCHNEDLER, Steven, C.  
Carter & Schnedler, P.A.  
Suite 101  
56 Central Avenue  
P.O. Box 2985  
Asheville, NC 28802  
ETATS-UNIS D'AMERIQUE

<b>Date of mailing (day/month/year)</b> 30 January 2001 (30.01.01)	
<b>Applicant's or agent's file reference</b> SEA-6-7-PCT	<b>IMPORTANT NOTIFICATION</b>
<b>International application No.</b> PCT/US00/08354	<b>International filing date (day/month/year)</b> 30 March 2000 (30.03.00)

1. The following indications appeared on record concerning:

☒ the applicant
 ☐ the inventor
 ☐ the agent
 ☐ the common representative

Name and Address

SHOFNER ENGINEERING ASSOCIATES, INC  
725 Pellissippi Parkway  
Knoxville, TN 37922  
United States of America

State of Nationality

US

State of Residence

US

Telephone No.

(865) 966-2732

Facsimile No.

(865) 966-2750

Teleprinter No.

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

☐ the person
 ☐ the name
 ☒ the address
 ☐ the nationality
 ☐ the residence

Name and Address

SHOFNER ENGINEERING ASSOCIATES, INC.  
Suite 215  
9737 Coghill Road  
Knoxville, TN 37932  
United States of America

State of Nationality

US

State of Residence

US

Telephone No.

(865) 966-2732

Facsimile No.

(865) 966-2750

Teleprinter No.

3. Further observations, if necessary:

4. A copy of this notification has been sent to:

☒ the receiving Office
 ☐ the designated Offices concerned  
☐ the International Searching Authority
 ☒ the elected Offices concerned  
☒ the International Preliminary Examining Authority
 ☐ other:

The International Bureau of WIPO  
34, chemin des Colombettes  
1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14.35

Authorized officer

Lazar Joseph Panakal

Telephone No.: (41-22) 338.83.38

# PATENT COOPERATION TREATY

**PCT**

## NOTIFICATION OF THE RECORDING OF A CHANGE

(PCT Rule 92bis.1 and  
Administrative Instructions, Section 422)

From the INTERNATIONAL BUREAU

To:

SCHNEDLER, Steven, C.  
Carter & Schnedler, P.A.  
Suite 101  
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<b>Date of mailing (day/month/year)</b> 30 January 2001 (30.01.01)	
<b>Applicant's or agent's file reference</b> SEA-6-7-PCT	<b>IMPORTANT NOTIFICATION</b>
<b>International application No.</b> PCT/US00/08354	<b>International filing date (day/month/year)</b> 30 March 2000 (30.03.00)

<b>1. The following indications appeared on record concerning:</b> <input type="checkbox"/> the applicant <input type="checkbox"/> the inventor <input checked="" type="checkbox"/> the agent <input type="checkbox"/> the common representative		
<b>Name and Address</b> SCHNEDLER, Steven, C. Carter & Schnedler, P.A. Suite 103 56 Central Avenue P.O. Box 2985 Asheville, NC 28802 United States of America	<b>State of Nationality</b>	<b>State of Residence</b>
	<b>Telephone No.</b> 828-252-6225	
	<b>Facsimile No.</b> 828-252-6316	
	<b>Teleprinter No.</b>	
<b>2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:</b> <input type="checkbox"/> the person <input type="checkbox"/> the name <input checked="" type="checkbox"/> the address <input type="checkbox"/> the nationality <input type="checkbox"/> the residence		
<b>Name and Address</b> SCHNEDLER, Steven, C. Carter & Schnedler, P.A. Suite 101 56 Central Avenue P.O. Box 2985 Asheville, NC 28802 United States of America	<b>State of Nationality</b>	<b>State of Residence</b>
	<b>Telephone No.</b> 828-252-6225	
	<b>Facsimile No.</b> 828-252-6316	
	<b>Teleprinter No.</b>	
<b>3. Further observations, if necessary:</b>		
<b>4. A copy of this notification has been sent to:</b> <div style="display: flex; justify-content: space-between;"> <div> <input checked="" type="checkbox"/> the receiving Office  <input type="checkbox"/> the International Searching Authority  <input checked="" type="checkbox"/> the International Preliminary Examining Authority                         </div> <div> <input type="checkbox"/> the designated Offices concerned  <input checked="" type="checkbox"/> the elected Offices concerned  <input type="checkbox"/> other:                         </div> </div>		

<b>The International Bureau of WIPO</b> 34, chemin des Colombettes 1211 Geneva 20, Switzerland	<b>Authorized officer</b>  Lazar Joseph Panakal
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

09/997584 (5310)

PATENT COOPERATION TREATY

REC'D 24 SEP 2001


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## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference <b>SEA-6-7-PCT</b>	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. <b>PCT/US00/08354</b>	International filing date (day/month/year) <b>30 March 2000 (30.03.2000)</b>	Priority date (day/month/year) <b>31 March 1999 (31.03.1999)</b>
International Patent Classification (IPC) or national classification and IPC <b>IPC(7): A61M 11/00 and US Cl.: 128/200.18</b>		
Applicant <b>Shofner Engineering Associates, Inc.</b>		
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>5</u> sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of <u>0</u> sheets.</p> <p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the report</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input type="checkbox"/> Non-establishment of report with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input checked="" type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p>		
Date of submission of the demand <b>31 October 2000 (31.10.2000)</b>	Date of completion of this report <b>18 September 2001 (18.09.2001)</b>	
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703)305-3230	Authorized officer <b>John Weiss</b>  Telephone No. 703-308-0858	

Form PCT/IPEA/409 (cover sheet)(July 1998)

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TECHNOLOGY CENTER R0700

**I. Basis of the report****1. With regard to the elements of the international application:\***

- ☒ the international application as originally filed.
- ☒ the description:  
pages 1-32 as originally filed  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_.
- ☒ the claims:  
pages 33-41, as originally filed  
pages NONE, as amended (together with any statement) under Article 19  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_.
- ☒ the drawings:  
pages 1-15, as originally filed  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_.
- ☐ the sequence listing part of the description:  
pages NONE, as originally filed  
pages NONE, filed with the demand  
pages NONE, filed with the letter of \_\_\_\_\_.

**2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.**

These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

**3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:**

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

**4. ☐ The amendments have resulted in the cancellation of:**

- ☐ the description, pages NONE
- ☐ the claims, Nos. NONE
- ☐ the drawings, sheets/fig NONE

**5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\***

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International Publication No.  
PCT/US00/08354**V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. STATEMENT**

Novelty (N)	Claims <u>1-14,23,28-33</u>	YES
	Claims <u>15-22,24-27</u>	NO
Inventive Step (IS)	Claims <u>1-14,23,28-33</u>	YES
	Claims <u>15-22,24-27</u>	NO
Industrial Applicability (IA)	Claims <u>1-33</u>	YES
	Claims <u>NONE</u>	NO

**2. CITATIONS AND EXPLANATIONS**

Claims 15,16 and 18-22 lack novelty under PCT Article 33(2) as being anticipated by Barrington, et al-'258. Barrington discloses an aerosol generator having a metering pocket 24 holding powder, a jet 30 and a mixing chamber 25.

Claims 15-22 and 26 lack novelty under PCT Article 33(2) as being anticipated by Newhouse, et al-'947. Newhouse discloses an aerosol generator having a metering pocket 52 holding powder, a jet produced by plunger 54 and piston 50 and a mixing chamber 34. the megadose disc is shown in fig. 5.

Claims 15,16 and 18-22 lack novelty under PCT Article 33(2) as being anticipated by Century-'412. Century discloses an aerosol generator having a powder dose actuated by a jet manufactured by a syringe or some other pulsed air or compressed air. A bolus or puff of powder is produced in a mixing chamber downstream of the metering pocket.

Claims 15,16-22 and 24-26 lack novelty under PCT Article 33(2) as being anticipated by Ambrosio, et al-'434. Ambrosio discloses an aerosol generator having a powder disc with a plurality of pockets of powder which are actuated by a jet to produce a mist of powder particles.

Claim 27 lacks novelty under PCT Article 33(2) as being anticipated by Ingebrethsen-5388574. Ingebrethsen discloses a device having a liquid solution which contains a powder drug in a volatile solvent. An atomizer atomizes the solution and the droplets leave a bolus directed into a mixing chamber 50.

Claims 1-14,23 and 28-33 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest a system for delivery and deposition of aerosolized masses including an aerosol generator, an upstream electro-optical mass concentration sensor, a gas flow sending aerosols past the sensor at a flow rate, a deposition zone, a downstream mass concentration sensor, a conduit sending uncollected aerosols past the second sensor at a flow rate, and a controller connected to the sensors for determining the net mass of collected aerosols; or an aerosol generator having the limitations of claim 16 additionally including a powder chamber, a sealing gland separating the powder and mixing chambers and the metering pocket includes a scoop in the tip of a plunger rod which passes through the powder chamber to load powder therein and then penetrates the sealing gland; or a deposition zone including a porous collector, an aerosol delivery tube against an upstream side of the collector and a perforated support against a downstream side of the collector; or a deposition zone having an impactor plate, an impactor jet depositing aerosols against the plate, and an output conduit conveying fluid and aerosols not deposited on the impactor plate.

----- NEW CITATIONS -----

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US00/08354

## VI. Certain documents cited

### 1. Certain published documents (Rule 70.10)

Application No Patent No.	Publication Date (day/month/year)	Filing Date (day/month/year)	Priority date (valid claim) (day/month/year)
6,234,169 A	22 May 2001 (22.05.2001)	14 August 1998 (14.08.1998)	None

### 2. Non-written disclosures (Rule 70.9)

Kind of non-written disclosure	Date of non-written disclosure (day/month/year)	Date of written disclosure referring to non-written disclosure (day/month/year)

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International Application No.  
PCT/US00/08354

## Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

### Continuation of Certain Documents Cited

#### 1. Certain published documents (Rule 70.10)

Application No

Publication Date

Filing Date

Priority date (valid claim)

Patent No.

(day/month/year)

(day/month/year)

(day/month/year)

None

None

None

None

#### 2. Non-written disclosures (Rule 70.9)

Kind of non-written disclosure

Date of non-written disclosure

Date of written disclosure referring to  
non-written disclosure

(day/month/year)

(day/month/year)

None

None

None



**FOR THE PURPOSES OF INFORMATION ONLY**

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
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EE	Estonia	LR	Liberia	SG	Singapore		

# INTERNATIONAL SEARCH REPORT

Inte Application No  
PCT/US 00/08354

A. CLASSIFICATION OF SUBJECT MATTER  
IPC 7 B05B7/14 B05B12/08

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)  
IPC 7 B05B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 826 386 A (MINNESOTA MINING & MFG) 4 March 1998 (1998-03-04) column 17, line 40 -column 18, line 45 ----	15
X	US 4 872 786 A (BRADEN THOMAS M) 10 October 1989 (1989-10-10) column 6, line 5 -column 7, line 45; figures 2,3,5,6 ----	15
X	DE 195 00 726 A (FRAUNHOFER GES FORSCHUNG) 18 July 1996 (1996-07-18) the whole document ----	15
X	US 5 567 472 A (JANSON JOHN P ET AL) 22 October 1996 (1996-10-22) column 2, line 45 -column 3, line 55 ----- -/--	30

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

### \* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- "&" document member of the same patent family

Date of the actual completion of the international search

1 August 2000

Date of mailing of the international search report

11/08/2000

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
Fax: (+31-70) 340-3016

Authorized officer

Polesak, H

# INTERNATIONAL SEARCH REPORT

Int. Patent Application No.  
PCT/US 00/08354

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 864 849 A (RID CORP) 16 September 1998 (1998-09-16) ---	
A	EP 0 789 230 A (TRANSPOWDER LTD) 13 August 1997 (1997-08-13) ---	
A	US 5 248 448 A (WALDRON J DAVID ET AL) 28 September 1993 (1993-09-28) ---	
A	US 5 263 475 A (ALTERMATT DANIEL ET AL) 23 November 1993 (1993-11-23) -----	

# INTERNATIONAL SEARCH REPORT

Information on patent family members

Int. Application No

PCT/US 00/08354

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 0826386 A	04-03-1998	AU 2513092 A BR 9206429 A CA 2114726 A DE 69230179 D EP 0601071 A ES 2137194 T JP 6509958 T MX 9204925 A WO 9303785 A US 6029661 A ZA 9206420 A	16-03-1993 24-10-1995 04-03-1993 25-11-1999 15-06-1994 16-12-1999 10-11-1994 01-02-1993 04-03-1993 29-02-2000 22-03-1993
US 4872786 A	10-10-1989	NONE	
DE 19500726 A	18-07-1996	NONE	
US 5567472 A	22-10-1996	US 5558713 A AU 4137496 A CA 2203137 A EP 0789627 A JP 10507967 T WO 9613335 A	24-09-1996 23-05-1996 09-05-1996 20-08-1997 04-08-1998 09-05-1996
EP 0864849 A	16-09-1998	JP 10096657 A WO 9813673 A	14-04-1998 02-04-1998
EP 0789230 A	13-08-1997	DE 19703842 A US 6010038 A	30-10-1997 04-01-2000
US 5248448 A	28-09-1993	US 4992206 A US 5439173 A	12-02-1991 08-08-1995
US 5263475 A	23-11-1993	AU 650953 B AU 1219292 A BG 60308 B BR 9200984 A CA 2076938 A CS 9200822 A CU 22354 B EP 0505321 A FI 921168 A HR 950142 A HU 67163 A, B IL 101289 A JP 5103835 A MX 9201185 A NO 921110 A NZ 242061 A PL 169776 B RO 108648 A SI 9210252 A SK 279020 B RU 2080129 C ZA 9202050 A	07-07-1994 24-09-1992 27-05-1994 17-11-1992 01-03-1993 14-10-1992 07-03-1995 23-09-1992 22-09-1992 30-04-1997 28-02-1995 14-05-1996 27-04-1993 01-10-1992 22-09-1992 27-09-1993 30-08-1996 29-07-1994 28-02-1995 06-05-1998 27-05-1997 28-10-1992